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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/694,037
Filing Date: October 27, 2003
Appellant(s): CLAGUE ET AL.

Rudolph Hofmann
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 15, 2009 appealing from the Office action mailed December 11, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,314,440	Shapiro	5-1994
6,036,641	Taylor et al.	3-2000

6,387,108

Taylor et al.

5-2002

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claims 1-3 and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (U.S. 5,314,440) in view of Taylor et al. (US 6,387,108).

Regarding claims **1 and 18**, Shapiro discloses a vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising: an elongated instrument shaft (12) extending between a shaft proximal end and a shaft distal end (Fig. 1) and having an instrument shaft axis (longitudinal axis) the elongated instrument shaft comprising a fixed or first shaft member (60) and a movable or second shaft member (62) adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis (col.4, lines 8-38); a first or fixed cutting blade (70) fixed to the first or fixed shaft member (60) at the shaft distal end to extend substantially laterally to the instrument shaft axis to a first or fixed cutting blade free end, the first or fixed cutting blade (70) having a blunt distal leading blade side, which includes a major portion spaced-apart from the cutting tip and the major portion of the blunt distal leading blade side (rounded distal side of 70 and straight edge of (66)), a proximal, trailing side having a first or fixed cutting edge (72), and a cutting tip (sharp pointed tip of 72) at the fixed cutting blade free end; a second or movable cutting blade (74) having a distal, leading edge (76) fixed to the

second or movable shaft member (62) at the shaft distal end (68), the second or movable cutting blade extending substantially laterally to the shaft axis and having a second or movable cutting edge along the second or movable cutting blade distal, leading edge (Fig.2); means for maintaining the second or movable shaft 62 member in a retracted position with the second or movable cutting blade spaced proximally from the first or fixed cutting member (spring 48, Fig. 2, col. 3, lines 15-25); and means (piston 20, Fig. 2, col. 3, lines 5-25) for moving the movable shaft member with respect to the fixed shaft member (60) between the retracted position separating the fixed and movable cutting edges (piston 20, Fig. 2) and an extended position wherein the first and second or fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein (Fig.3).

Still regarding claims **1 and 18**, noting that Shapiro discloses (Fig. 2) the fixed cutting edge (72) of the proximal trailing side is generally angle along the direction of the laterally extending fixed cutting blade (70), however, Shapiro fails to disclose the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade and the major portion of blunt distal leading blade side extends generally perpendicular to the proximal trailing side. However, Taylor et al. disclose such a feature. Figure 6b (reproduced below this paragraph) discloses a fixed cutting blade having a fixed cutting edge which generally straight along the direction of the laterally extending fixed cutting blade and the major portion of blunt distal leading blade side extends generally perpendicular to the proximal trailing side. Since it has been held the simple substitution of one known element for another to obtain

predictable results is old and well known in the art, therefore, it would have been obvious to modify the fixed cutting blade (72) and moveable cutting blades (74) of Shapiro according the suggestion of Taylor et al in order to gain the advantage of minimize pressure of the blade exert on the eye during puncturing of the eye.

The statement of intended use: "as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel" has been carefully considered but deemed not to impose an structural limitations on the apparatus claims. The device of Shapiro is capable of being used as claimed if one desired to do so.

Regarding **claims 2 and 19**, the first or fixed cutting blade (70) is disposed to extend laterally to the shaft axis by a shank (66) having a shank proximal end mounted to the first or fixed shaft member (60) at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the movable cutting blade to a shank distal end (fig. 2); and the first or fixed cutting blade (70) extends laterally to the shaft axis from the shank (66) distal end to the fixed cutting blade free end and has a substantially straight fixed cutting edge (fig. 2).

The statement of intended use: "whereby the cutting tip at the fixed cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body

vessel" is capable of being performed by the device of Shapiro and once again not given any weight in the absence of any structural limitations.

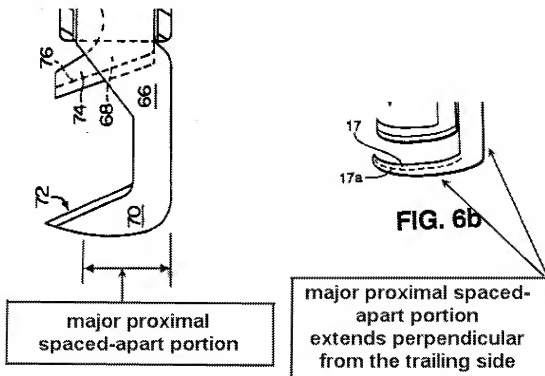
Regarding **claims 3 and 20**, the means for maintaining the first and second shaft members in a retracted position (fig. 2) comprises a spring (48) mounted between the first and second or fixed and movable shaft member and exerting retraction force there between (col.3, lines 22-25); and the moving means comprises means for transmitting force overcoming the retraction force to the second or movable shaft member to move the movable shaft member with respect to the first or fixed shaft member between the retracted position and the extended position (figs. 2 & 3; col.4, lines 23-45).

Claims 4-6, 15-17, 21-23 and 32-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro in view of Taylor et al. (US 6,387,108) as applied to claims 1 and 18 above and further in view of Taylor et al (US 6,036,641).

Shapiro discloses the invention substantially as claimed above, but fails to disclose stabilization means in combination with the vessel wall cutting instrument. However, Taylor teaches various stabilization means including a means for suction (col.16, lines 18-21), an occlusion frame (figs. 10C and 36), and a means to apply compressive force (fig. 37A; col.29, lines 40-50). Apparently the advantage of the stabilization means as taught by Taylor is for beating heart coronary artery bypass graft procedure (CABG). Therefore, it would have been obvious to a person of ordinary skill in the art to further utilizing the device of Shapiro by incorporate the stabilizing means as taught by Taylor et al. (US 6,036,641) so that it too would have the advantage.

(10) Response to Argument

Appellant argues, in pages 8-9 of the appeal brief, that incorporation of the hook-shaped sharp tip as disclosed by Taylor into the cutting edge of Shapiro will cause damage to the endothelial, which is the inside layer of blood vessel, layer of the vessel. Examiner respectfully traverses appellant remarks, noting that the fixed cutting edge (72) of Shapiro already has a cutting tip located at the free end of cutting edge (72). Therefore, there is no need to incorporate the hook cutting tip of Taylor into the cutting edge (72) in order to penetrate the eyes during an ophthalmic surgery. Examiner relies on Taylor reference for the teaching of the fixed cutting edge of the proximal trailing side which is generally straight along the direction of the laterally extending fixed cutting blade and the major portion of blunt distal leading blade side extending generally perpendicular to the proximal trailing side (see Fig. 6b, reproduced below this paragraph) to modify the cutting blades of Shapiro in order to gain the advantage of minimize pressure of the blade exerted on the eye during puncturing of the eye.



Appellant argues, in page 10 of the appeal brief, that Taylor fails disclose the limitation of "wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side" because the blade stop of Taylor is essentially the same width through its length and no major portion is spaced-apart from the tip to meet these claim features. Examiner respectfully traverses appellant remarks. Note that the fixed cutting edge (72) of Shapiro already has a blunt distal leading blade side which includes a major portion spaced-apart from the cutting tip (see Examiner's interpretation of this limitation shown in Fig. 2, reproduced above this paragraph). Examiner relies on the Taylor reference for the teaching of the fixed cutting edge of the proximal trailing side which is generally straight along the direction of the laterally extending fixed cutting

blade and the major portion of blunt distal leading blade side which extends generally perpendicular to the proximal trailing side (see Fig. 6b, reproduced in page 8) to modify the cutting blades of Shapiro in order to gain the advantage of minimize pressure of the blade exert on the eye during puncturing of the eye. Shapiro as modified by Taylor still has the blunt distal leading blade side which includes a major portion spaced-apart from the cutting tip. Furthermore, the major portion spaced-apart from the sharp tip is now extending generally perpendicular to the proximal trailing side.

(11) Related Proceeding(s) Appendix

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Tuan V Nguyen/
Examiner, Art Unit 3731

Conferees:

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

/Heather Shackelford/
Conferee